UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

Sandra Anderson,

Plaintiff,

v. Civil Action No. 5:09-CV-16

Kathleen Sebelius, Secretary of Health and Human Services,

Defendant.

REPORT AND RECOMMENDATION
(Docs. 30, 34)

Plaintiff Sandra Anderson brings this action against Defendant Kathleen Sebelius, Secretary of the United States Department of Health and Human Services ("Secretary"), under 42 U.S.C. §§ 405(g) and 1395ff(b)(1) to review the Secretary's decision denying Anderson coverage under the Medicare Part A program for home health services. Presently before the Court are Anderson's Motion for an Order Reversing the Secretary's Decision (Doc. 30), and the Secretary's Motion to Affirm the same (Doc. 34). For the reasons set forth below, I recommend that Anderson's Motion be GRANTED, and that the Secretary's Motion be DENIED.

Background

Sandra Anderson began receiving home health services from the Visiting Nurse Association of Chittenden and Grand Isle Counties ("VNA") on June 7, 2004. She was 60 years old at the time, and had just returned home after being hospitalized for her

second stroke. She suffered from urinary incontinence, "acute, but ill-defined" cerebrovascular disease, hypertension, cognitive impairments including memory deficit, limited physical mobility, slurred speech, and newly diagnosed type II diabetes. (AR 175-76, 256.) Because of her cognitive impairments and immobility, Anderson required 24-hour supervision to remain safe in her home environment. (AR 172.)

Ms. Anderson's treating physician, Dr. Stephen Mann, certified a variety of skilled nursing services for Anderson that included skilled diabetic foot care, patient education on diabetes management and a diabetic diet, overall management and evaluation of her care plan, and observation and assessment of her condition. In addition, Anderson received physical and occupational therapy, medical social services provided by a social worker, and non-skilled personal care. (*See*, *e.g.*, AR 170-73.) Dr. Mann certified (and re-certified) this care for six 60-day certification periods from June 7, 2004 to June 2, 2005. (AR 170, 605, 915, 1238, 1386.) While care was certified into June 2005, Anderson's occupational therapy concluded on September 12, 2004 (AR 216), and she was discharged from physical therapy on December 2, 2004 (AR 643-44).

Associated Hospital Service, the fiscal intermediary tasked with making the initial coverage determination in this case,[1] covered the services provided to Anderson during the first certification period of June 7 to August 6, 2004, but denied coverage for the remaining five periods. (AR 343, 728, 862, 1183.) The intermediary upheld the denials

[1] The Center for Medicaid and Medicare Services ("CMS"), which is the federal agency within HHS that administers the Medicare program, contracts out its claim processing to private companies referred to as "fiscal intermediaries." Fiscal intermediaries are required to reimburse providers only for those items and services covered by Medicare. *See generally Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 73 (2d Cir. 2006).

on reconsideration, and Maximus Federal Services, a Medicare "Qualified Independent Contractor" ("QIC"), affirmed on October 30, 2007. (AR 123, 562, 861, 1182.)

Anderson then sought review by an Administrative Law Judge ("ALJ"), and a hearing was held on February 12, 2008 with Anderson's counsel appearing via video teleconference. (AR 1385-99.) In separate decisions dated February 19, 2008, the ALJ affirmed the denial of coverage for all five of the challenged certification periods, finding that "[t]he home health services provided to Sandra Anderson . . . did not meet Medicare coverage criteria." (AR 54, 497, 787, 1110.) However, the ALJ also waived Anderson's liability because the VNA did not sufficiently notify Anderson that Medicare would not cover her services. *Id*.; *see* 42 U.S.C. § 1395pp(b). This disposition left the VNA solely responsible for the uncovered service charges.[2] Anderson then appealed the denial of coverage for the second, third, fourth, and fifth periods (August 7, 2004 to April 3, 2005) to the Medicare Appeals Council ("MAC"), and the MAC, in what constitutes the Secretary's final decision, affirmed the ALJ's decisions on November 20, 2008. (AR 5.)

[2] Although Anderson was not left financially liable for the VNA services, she retains standing to sue in federal court. She meets the amount in controversy threshold of 42 U.S.C. § 1395ff(b)(1)(E) because 42 C.F.R. § 405.1006(d)(2) provides that, when the beneficiary's liability is limited, the amount in controversy is "the amount the beneficiary would have been charged." And Anderson suffered an injury-in-fact because, if her coverage denial is upheld in this case, she will be presumed for subsequent coverage issues to have knowledge that the services will not be covered. *See* 42 U.S.C. § 1395pp(b); *Dennis v. Shalala*, 1994 WL 708166, at *1 n.1 (D. Vt. Mar. 4, 1994). In addition, Congress has provided that a beneficiary is the sole person who may bring an appeal when his or her coverage is denied, and that a provider found liable (such as the VNA in this case) may exercise those rights "only after the Secretary determines that the [beneficiary] will not[.]" 42 U.S.C. § 1395pp(d); *see also Massachusetts v. EPA*, 549 U.S. 497, 516 (2007) ("Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before.") (internal quotation marks omitted).

Having exhausted all of her administrative remedies, Anderson commenced this suit against the Secretary on January 16, 2009. (Doc. 3, Compl.)

Standard of Review

Judicial review of the Secretary's decision to deny Medicare coverage is limited to determining whether substantial evidence supports the Secretary's factual findings, and whether the Secretary applied the correct legal standards in reaching her decision. 42 U.S.C. § 405(g); *Johnson v. Bowen*, 817 F.2d 983, 985 (2d Cir. 1987). Substantial evidence "means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Gartmann v. Sec'y of Health & Human Servs.*, 633 F. Supp. 671, 679 (E.D.N.Y. 1986). This standard provides significant deference to the Secretary's factual findings, and is more deferential than even the "clearly erroneous" standard. *See Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). To determine whether substantial evidence exists, the reviewing court analyzes the record as a whole, meaning that it "will not look at [evidence supporting the Secretary's position] in isolation but rather will view it in light of other evidence that detracts from it." *Bodnar v. Sec'y of Health & Human Servs.*, 903 F.2d 122, 126 (2d Cir. 1990).

While the reviewing court must defer to the Secretary's supported findings of fact, it "is not bound by the Secretary's conclusions or interpretations of law, or an application of an incorrect legal standard." *Gartmann*, 633 F. Supp. at 679. Therefore, "[b]efore the insulation of the substantial evidence test comes into play, it must first be determined that the facts of a particular case have been evaluated in light of correct legal standards." *Id.* at 680 (internal quotation marks omitted).

Discussion

Anderson seeks reversal of the Secretary's decision denying coverage for services provided in the four certification periods spanning August 7, 2004 to April 3, 2005. Her Complaint lists three separate causes of action. First, Anderson claims that the Secretary violated the applicable statutory, regulatory, and policy manual provisions by applying an "informal," "secret," and "unlawful" presumption—hereafter the "stability presumption"—that coverage should be automatically denied for patients with chronic or stable conditions. (Doc. 3, Compl. ¶ 33; 12 at 2; 30-1 at 5.) Second, Anderson claims that application of this unlawful presumption, or "rule of thumb," violated her Fifth Amendment Due Process rights. (Doc. 3 ¶ 34.) Third, Anderson claims that substantial evidence does not support the Secretary's factual findings. *Id*. ¶ 35. In addition to reversal, Anderson seeks a declaration that the Secretary's secret stability presumption violates the Due Process Clause of the Fifth Amendment, as well as a "permanent injunction and a writ of mandamus prohibiting the defendant" from applying that presumption to Anderson and all other beneficiaries. *Id*. at 8-9.

As explained below, the Court finds that the ALJ did not presumptively deny coverage because of Anderson's "chronic stability," and therefore did not violate Anderson's Due Process rights. But reversal and remand are nonetheless warranted because the ALJ committed other legal error and rendered findings that are unsupported by substantial evidence.

I. Legal Framework

The Medicare program, established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, "is the federal government's health-insurance program for the elderly." *Conn. Dept. of Soc. Servs. v. Leavitt*, 428 F.3d 138, 141 (2d Cir. 2005). Pertinent here, Medicare Part A is an automatic and premium free program that "provides basic insurance protection against the costs of hospital, related post-hospital, home health services, and hospice care." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 73 (2d Cir. 2006). The fundamental requirement for Part A Medicare coverage is that the provided items and services be "reasonable and necessary for the diagnosis or treatment of illness or injury[.]" 42 U.S.C. § 1395y(a)(1)(A).

To receive Medicare benefits for home health care services—the services for which Anderson seeks coverage in this case—a beneficiary must be (a) confined to the home; (b) under the care of a physician; (c) in need of skilled services; and (d) under a plan of care. 42 C.F.R. § 409.42(a)-(d). The sole issue here is whether Anderson was in need of skilled nursing and therapeutic services throughout the relevant time period—that is, whether she received compensable skilled services and whether such services were "reasonable and necessary." (Docs. 30-1 at 5; 34 at 5.)

Skilled nursing care "consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse," 42 C.F.R. § 409.44(b)(1), and excludes services that can "safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse[.]" 42 C.F.R. § 409.99(b)(1)(i)-(ii). In determining whether a service is "skilled," "consideration must be

given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice[.]" *Id*. A nursing service is considered skilled based solely on its inherent complexity, and without regard to the patient's condition, if it is "so inherently complex that it can be safely and effectively performed only by, or under the supervision of," a licensed nurse. 42 C.F.R. §§ 409.32(a)-(b); *Medicare Benefit Policy Manual* (*MBPM*), CMS Pub. 100-02, § 40.1.1. And "in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered [skilled]." *MBPM* § 40.1.1. Overall management and evaluation of a care plan, observation and assessment of a patient's changing condition, and patient education services may, under certain circumstances, constitute skilled care. *See* 42 C.F.R. § 409.33(a)(1)-(3).

To be reasonable and necessary, the skilled "services must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice." 42 C.F.R. § 409.44(b)(3)(i). Applying this standard requires an individualized assessment of the patient's needs, that is, "[t]he determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness is acute, chronic, terminal, or expected to last a long time." 42 C.F.R. § 409.44(b)(3)(iii); *see also* 42 C.F.R. § 409.44(a) ("A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally

but is based upon objective clinical evidence regarding the beneficiary's individual need for care.").

Therapeutic services (including physical and occupational therapy) constitute covered skilled services when they are "of such a level of complexity and sophistication or the condition of the beneficiary [is] such that the services required can safely and effectively be performed only by a qualified [therapist]." 42 C.F.R. § 409.44(c)(2)(ii). In addition, these services must meet one of three requirements:

> There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition, or the services must be necessary to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program.

42 C.F.R § 409.44(c)(2)(iii). As with skilled nursing services, the need for physical and occupational therapy must be assessed in light of a patient's individual needs, and a "patient's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled." *MBPM* § 40.2.1. Instead, "[t]he key issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by nonskilled personnel." *Id*.

Finally, "dependent services," which include the social services furnished by a qualified social worker to Anderson in this case (AR 51), are not independently covered by Medicare. 42 C.F.R. § 409.45(a)-(g). Such services are covered only if the beneficiary qualifies for the coverage of skilled home nursing or therapeutic services. 42 C.F.R. § 409.45(a); *see also* 42 C.F.R. § 409.42.

II. The ALJ did not Apply an Improper Presumption or "Rule of Thumb"

Anderson's primary argument is that the ALJ failed to consider her individual needs, and instead applied an unlawful presumption that Medicare coverage should be denied for all patients whose condition is chronic or stable. (Doc. 30-1 at 5.) She argues that this stability presumption contradicts Medicare regulations requiring individualized assessments and explicitly proscribing the denial of coverage based solely on a patient's stability. *Id*. In response, the Secretary does not dispute that such a rule, were it applied, would constitute legal error. (Doc. 34 at 7-8.) But the Secretary contends that no such rule was applied here, and that the ALJ's stated rationales supporting her conclusions are either fully consistent with governing law, or constitute harmless error. *Id*. at 7-9. While the Court finds other error warranting reversal, it agrees with the Secretary that the record does not reveal an "illegal chronic rule of thumb" or stability presumption.

Nowhere does the ALJ state that she is applying a presumptive coverage screen against patients with unchanging conditions, but Anderson infers its use from the ALJ's observations that "the Beneficiary has no documented clinical instability," and "[t]here are no documented changes in medications, changes in the plan of care, or changes in the Beneficiary's baseline medical status that required skilled intervention." (AR 52, 495, 785, 1109.) Anderson argues that the ALJ's reliance on her "chronic" condition "pervaded the ALJ's legal analysis, and resulted in four separate but interrelated errors of law"—one for each type of service deemed not covered based on this rule. (Doc. 30-1 at 7.)

This would be a different case had the ALJ denied coverage for all services based on these observations alone. Both Parties agree, and the regulations could not be clearer in stating, that coverage determinations must generally be made "without regard to whether the illness or injury is acute, chronic, terminal or expected to last a long time." 42 C.F.R. § 409.44(b)(3)(iii). But Anderson's argument fails because she received certain skilled services for which patient stability is directly relevant, and, as explained in more detail below, the ALJ did not rely on Anderson's "chronic stability" to deny coverage for every service that the VNA provided. To find otherwise would contravene the Second Circuit's admonition that courts may not "ascribe . . . nefarious motives on an agency action as a general matter." *Estate of Landers v. Leavitt*, 545 F.3d 98, 113 (2d Cir. 2008).

A. The ALJ Did Not Presumptively Deny Coverage for Skilled Foot Care

There is no suggestion in her decisions that the ALJ denied coverage for skilled diabetic foot care because Anderson was "chronically stable." Indeed, and notwithstanding the ALJ's finding that Anderson was "chronic" and "stable," the ALJ acknowledged that Anderson "needed skilled foot care on October 5, 2004," but denied coverage because Anderson "was scheduled for an appointment with her podiatrist for the needed care" and "[n]onskilled personnel could have scheduled the needed appointment." (AR 52, 495.) Thus, the ALJ looked beyond Anderson's stability to recognize that she required skilled foot care, but denied coverage because that requirement was being met on an outpatient basis by a podiatrist.

Anderson counters that, setting aside those instances in which she received care from a podiatrist, the ALJ "gave no explanation for rejecting the skilled footcare that *was* provided by a skilled nurse." (Doc. 30-1 at 9.) This assertion is unavailing for two reasons. First, while it is true that the record contains limited references by VNA nurses to "skilled foot care" and "skilled toe nail care," AR 183 ("some skilled toe nail care . . . will make appt. [with] podiatrist"); AR 1245 ("skilled foot care done"), the nursing notes reveal that Anderson was routinely referred to a podiatrist or to Dr. Mann for her foot care treatment. *See*, *e.g.*, AR 179-80 (reddened, sore toe noted and Dr. called); AR 183 (nurse "unable to trim [nails] . . . will make appt. [with] podiatrist); AR 184 ("need podiatrist appointment for nail care"); AR 619 (nurse calls M.D. to request podiatry appt. to trim nails); AR 937 ("Toenails need to be cut. Will leave message with case manager"); AR 923 (nurse cuts toenails and notes a future scheduled podiatry appt.). Thus, even assuming that vague references to "skilled foot care" are what they say they are, the relative infrequency with which they appear compared to podiatry and physician referrals sufficiently explains the ALJ's decision to specifically mention only the outpatient nature of Anderson's foot care in denying her coverage.

Second, even assuming that it was error for the ALJ to ignore the one specific reference to skilled foot care performed by a visiting VNA nurse (AR 1245), it does not follow that she did so because of an illegal presumption that chronically stable patients are not entitled to coverage for diabetic foot care. Not only would this conclusion contradict the ALJ's recognition that Anderson *was*, at least during certain periods, in

need of skilled foot care, it would also impermissibly attribute an agency error to a "nefarious motive" without sufficient evidence.[3] *Estate of Landers*, 545 F.3d at 113.

B. The ALJ Did Not Fail to Assess Anderson's Need for Skilled Management

Overall management and evaluation of a patient's care plan constitutes a skilled service "when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety." 42 C.F.R. § 409.33(a)(1)(i). Anderson claims that the ALJ failed to apply this regulation, instead denying coverage for care management solely because Anderson's "condition was chronically stable." (Doc. 30-1 at 10.) The ALJ's written decisions belie this conclusion.

There is simply no justification for finding a causal relationship between the ALJ's observations about Anderson's stability and the ALJ's conclusion that Anderson neither needed nor received skilled management of her care plan. To the contrary, the ALJ succinctly stated that Medicare did not cover this service because "[t]he personal care services provided to [Anderson] were not so complex that they required the management of professional personnel." (AR 52, 495, 785, 1109.) As it turns out (and as explained fully below in Part IV. C., *infra*), this explanation does not satisfy the regulations and case law governing coverage of care management, but it *does* refute Anderson's claim

[3] Anderson's reference to her initial "Decision Rationale" denying her coverage is similarly unavailing. The decision says that "the criteria for Medicare coverage [for foot care] was not met," and then, in the next sentence, observes that Anderson did not experience any changes in her condition. (Doc. 21-1.) But when read in its entirety, this Decision is plainly nothing more than a series of isolated, unrelated sentences, and there is no reason to think that one qualifies or explains the one preceding it.

that the ALJ denied coverage based solely on Anderson's chronic stability. Although there is legal error, there is no secret and illegal presumption that stabilized patients are not covered for the management and evaluation of their care plans.

C. The ALJ Did Not Presumptively Deny Coverage for Observation and Assessment of Anderson's Condition

Anderson argues that the ALJ's reliance on Anderson's stability also infected her analysis of whether Medicare covers the observation and assessment of Anderson's condition. This argument fails because the issue of whether Medicare covers observation and assessment depends, in part, on whether the patient's condition has stabilized. Observation and assessment of a patient's "*changing* condition" involves covered skilled services "when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification or treatment or for additional medical procedures *until his or her condition is stabilized*." 42 C.F.R. § 409.33(a)(2)(i) (emphasis added). In denying coverage for this service, the ALJ reasoned that "[t]he documentation does not support the likelihood of a future complication or acute episode, a reasonable potential for complications, or that [Anderson's] condition or treatment regimen was unstable and required continued observation and assessment by a skilled nurse." (AR 52, 495, 785, 1109.)

Anderson ostensibly objects to the same stability presumption in this context as well, but the plain language of the relevant regulation forces her to shift her argument. As the regulation makes clear—and as Anderson concedes—the observation and assessment of a patient's condition is only covered when there is a reasonable potential

for a complication or further acute episode, and *not* when the patient's condition is stable and unlikely to change. *MBPM* § 40.1.2.1; Doc. 30-1, Pl.'s Mem. at 13 ("The need for skilled observation and assessment . . . depends on whether a beneficiary's condition or care might be expected to change"). The purpose of observation is to ensure that skilled caregivers can "identify and evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures" arising from changes in the patient's condition. *Id*. Given this regulation, it was appropriate for the ALJ to discuss Anderson's stability in her analysis denying coverage for skilled observation.

Consequently, Anderson alters her objection to say that the ALJ erred by evaluating Anderson's need for skilled observation with the benefit of hindsight, rather than from the perspective of the attending physician at the time services were ordered. (Doc. 30-1 at 12-13.) She argues that the use of hindsight to deny coverage for patients whose condition proved stable is a symptom of the Secretary's stability presumption at work. Anderson is correct in her condemnation of hindsight as far as it goes. The Secretary agrees that services must be analyzed "from the perspective of the condition of the patient when the services were ordered and what was, at that time, reasonably expected to be appropriate treatment . . . throughout the certification period." (Doc. 34 at 11); *MBPM* § 40.1.1. And this Court has said repeatedly that the mere "fact that [the beneficiary] did not experience the complications sought to be avoided by the type of care described in §§ 409.33(a)(1)-(2) does not mean that those services were not reasonably expected to be appropriate treatment . . . and thus reasonable and necessary." *Smith on behalf of McDonald v. Shalala*, 855 F. Supp. 658, 664 (D. Vt. 1994); *Bergeron*

v. Shalala, 855 F. Supp. 665, 669 (D. Vt. 1994); *Folland on behalf of Smith v. Sullivan*, 1992 WL 295230, at *7 (D. Vt. Sept. 1, 1992).

But even if the ALJ violated this rule by assessing the stability of Anderson's condition with the benefit of hindsight, that is different from—and not necessarily symptomatic of—the alleged error of ignoring Anderson's individualized needs in favor of a presumption that stable patients are not covered by Medicare. It was appropriate for the ALJ to consider Anderson's stability in the context of observation and assessment, and the only issue is whether she made an impermissible *ex post facto* determination in so doing. Accordingly, Anderson's assertion of an illegal presumption or rule of thumb is not supported by the ALJ's denial of coverage for skilled observation and assessment.

D. The ALJ Did Not Presumptively Deny Coverage for Physical or Occupational Therapy

Similarly, Anderson argues that the ALJ applied her unwritten presumption when she improperly required an expectation of improvement for coverage of physical and occupational therapy, and failed to consider whether Anderson needed a skilled therapist to either "establish" or "perform" a maintenance program. (Doc. 30-1 at 7.) In Anderson's view, the ALJ's analysis concerning skilled therapy is yet another manifestation of her rule that coverage is automatically denied for patients whose condition is not changing. Although the ALJ provided an incomplete analysis and thus committed legal error, Anderson's claim of an illegal stability presumption is unsupported.

In her analysis, the ALJ applied the correct legal standard for evaluating *restorative* physical therapy, but failed to consider whether Anderson was covered for *maintenance* therapy. The ALJ incorrectly stated that Medicare covers therapeutic services only when they are "provided with the expectation, based on the assessment made by the physician of the patient's rehabilitation potential, that the condition of the patient will improve materially in a reasonable and generally predictable period of time." (AR 53, 496, 785-86.) Based on this formulation of the legal standard, the ALJ denied coverage for physical and occupational therapy solely because "it could not be expected that the condition of [Anderson] would improve," and "she was a poor rehabilitation candidate during the period in review."[4] (AR 53, 496, 786.) This analysis is inadequate because the ALJ ignored the possibility that Anderson needed skilled therapy to either establish or perform a maintenance program. 42 C.F.R. § 409.44(c)(2)(iii); *see also* Doc. 34, Def.'s Mem. at 9.

But as with the ALJ's failure to apply the correct law in assessing Anderson's need for skilled care management, this error is not indicative of an illegal presumption denying skilled therapy for those with unchanging conditions. In suggesting otherwise, Anderson ignores the record evidence showing that Dr. Mann ordered therapeutic

[4] The ALJ also commented that, "[o]n the basis of this record, I find the Beneficiary does not display material improvement from the start of care." (AR 53, 496, 786.) To the extent this means that coverage for physical therapy must be denied whenever the patient does not *actually* improve, the ALJ is mistaken. The relevant inquiry for restorative therapeutic services is whether the patient could have been *expected* to improve, assessed from the perspective of the patient's physician, and "based on the assessment made by the physician of the patient's rehabilitation potential[.]" 42 C.F.R. § 409.44(c)(2)(iii); *MBPM* § 40.2.1; *see also* Part IV. A., *infra*.

services for Ms. Anderson primarily—if not entirely—to *restore function*, and not merely to maintain her baseline level of functionality. For example, physician certifications from August 2004 indicate a home exercise program with the general goal for Anderson to "achieve maximum physical mobility within the limitations imposed by the disease," and to progress to the independent use of a cane. (AR 170-72.) And in October, Dr. Mann certified physical therapy to "progress to cane as feasible," (AR 605) and directed an "increase in complexity as tolerated." (AR 610.) Finally, Anderson was discharged from physical therapy, and Dr. Mann did not certify additional skilled therapy, once her functional mobility had "plateaued" (AR 643-44), further demonstrating that her physical therapy was for improvement, not maintenance. In light of this record, it was legally appropriate for the ALJ to assess whether Anderson was a "poor rehabilitation candidate," and to deny coverage for restorative therapy accordingly.[5] *See* 42 C.F.R. 409.44(c)(2)(iii). This record evidence also explains why the ALJ did not specifically analyze whether Anderson required skilled services to perform a maintenance program. While this omission was error, there is an insufficient basis to attribute that error to a secret and unlawful presumption.

III. The Secretary Did Not Violate Anderson's Due Process Rights

Anderson's Due Process claim is premised entirely on the Secretary's alleged practice of automatically denying coverage for patients with chronic or unchanging conditions. (Doc. 30-1 at 18-20.) She argues that this practice is procedurally unfair, and

[5] As explained in Part IV. A., *infra*, there is not substantial evidence to support the ALJ's determination that Anderson was a poor rehabilitation candidate with no expectation of improvement.

that the Fifth Amendment entitles beneficiaries to a decision making process that is untainted by secret presumptions and rules of thumb that are contrary to, and preclude proper application of, the governing legal standards. *Id*. (citing *Fox v. Bowen*, 656 F. Supp. 1236, 1249-50 (D. Conn. 1987)).

Having rejected Anderson's claim that the Secretary applied the alleged stability presumption in this case, Anderson's Due Process claim necessarily fails as well.

IV. Reversal and Remand are Appropriate Because of Other Legal Errors and Factual Findings Not Supported by Substantial Evidence

Although Anderson has not established a presumption denying coverage for stable patients, the ALJ committed other reversible errors in deciding that Anderson neither needed nor received skilled nursing services. Specifically, the ALJ's findings concerning physical and occupational therapy are not supported by substantial evidence, she did not properly consider Dr. Mann's physician certifications, and she failed to adequately evaluate whether Anderson required skilled management of her care and patient education.

A. Physical and Occupational Therapy

Anderson received physical therapy from a skilled physical therapist throughout the relevant period until December 2, 2004 (AR 643-44), and she received occupational therapy from August 13 to September 2, 2004 (AR 208, 210-16). The ALJ denied coverage for both services because Anderson "does not display material improvement from the start of care," and because "it could not be expected that [Anderson's condition] would improve materially in a reasonable and generally predictable period of time."

Given these findings, the ALJ concluded that Anderson "was a poor rehabilitation candidate during the period in review." (AR 53, 496, 786.)

The record contains no evidence—let alone substantial evidence—supporting these findings, and no reasonable fact finder could come to the same conclusion as that reached by the Secretary. Dr. Mann's certifications and the therapist treatment notes uniformly demonstrate both that Anderson was reasonably expected to improve, and in fact did improve, as a result of physical and occupational therapy.

The goal of Anderson's physical therapy was to increase her overall independence, and specifically to enable her to walk independently with a cane. (AR 172, 191, 193, 197, 610, 641, 833.) Dr. Mann recognized early improvement toward these ends on August 24, 2004, which was during the second overall certification period and the first at issue in this case. Dr. Mann noted that Anderson "now exhibits active motion [in lower] anterior tibialis and peroneals. . . . She has increased strength and control of [lower] extremities in general and should be able to progress to standard cane over time. . . . [I] [a]nticipate continued gains and eventual functional independence." (AR 170-72.) Nursing notes around this time document similar progress, explaining that Anderson was "ready to transition to cane but *not* safe to attempt alone. Cont[inues] to exhibit steady progress." (AR 193.) These observations are echoed in nursing notes from August 24 and August 31, which state that Anderson was not yet using a cane safely, but was "more stable overall" and showed no "indication of approaching plateau" as she became "more functionally indep[endent] [using a] walker." (AR 195, 197.)

In the next certification period, Dr. Mann continued to express satisfaction with Anderson's progress, and optimism regarding her rehabilitative potential. On October 20, 2004, he noted that Anderson "has progressed to tolerate trial of [cane] with [moderate assistance] on varied surfaces," and "has tolerated progressively complex challenges in standing balance and coordination while holding on to counter. [She] [c]ontinues to demonstrate rehab potential." (AR 606.) And two days later Dr. Mann observed that Anderson showed "improved balance," "independence with home exercise program," and "motivation towards achieving increased level of function." (AR 609.) Nursing notes from this time document more specific improvements in Anderson's ambulation using a cane, noting that Anderson was better with her cane and walking to 1200 feet (AR 631), a distance later increased to 2000 feet when walking on the driveway and yard. (AR 634, 636-37.)

Anderson was later discharged from physical therapy in December after becoming more functional in her activities of daily living and progressing in her use of a cane, though still requiring a walker to ambulate safely without any supervision. (AR 643-44.) And subsequently, notes from another physical therapist visiting Anderson after her "PT end date" reinforce that progress had been made, and that more progress was expected. These December 16 notes observe that she was capable of using a cane to walk 12 lengths of her home, and the plan going forward was "to begin cane walking in [about] one month [independently]." (AR 929.)

In sum, virtually all of the medical evidence supports the position that physical therapy was reasonably expected to materially improve Anderson's condition during the

periods when such services were ordered. In finding to the contrary, the ALJ relied exclusively on Anderson's OASIS assessments, which state that she "[r]equires use of a device (e.g., cane, walker) to walk alone or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces."[6] (AR 53, 176, 188, 623, 926.) But the bare assertion that Anderson required assistance to walk does not at all suggest that Anderson was either a poor rehab candidate or did not materially improve during her course of therapy. After all, Dr. Mann never intended for therapy to enable Anderson to walk *completely* unassisted, and the Secretary does not claim that the ability to walk with a cane is an insufficient goal for which Medicare will not provide coverage. And, in any case, this formulaic, boilerplate assertion so lacking in detail that it fails to make the important distinction between rolling walkers and canes (*see* AR 170, 177, 193, 197, 643-44), cannot reasonably outweigh the plethora of individualized and substantive record evidence demonstrating Anderson's rehab potential and improvement.

Finally, the Secretary's latest defense, that coverage for physical therapy was correctly denied because Anderson did not fully achieve her goal of walking independently with a cane, fails as a matter of law. (Doc. 34 at 18.) First, the regulations require only that patients be expected to "improve materially in a reasonable (and generally predictable) period of time," 42 C.F.R. § 409.44(c)(2)(iii), not that they must meet, or even be expected to meet, some particular stated goal. Second, even patients

[6] Medicare-certified home health agencies, such as the VNA, are required to use a standard set of data items, known as OASIS (Outcome and Assessment Information Set) as part of a comprehensive assessment for all patients who are receiving skilled care that is reimbursed by Medicare or Medicaid. http://www.cms.hhs.gov/OASIS/09a_hhareports.asp#TopOfPage.

who do not improve *at all* may nonetheless be covered for restorative physical therapy if, "based on the physician's assessment of the beneficiary's restoration potential," they were reasonably *expected* to improve at the time services were ordered. *Id*.

The record is also clear that Anderson improved from her course of occupational therapy, and there is no basis for the ALJ's conclusion that the "[t]reatment notes do not indicate any . . . reason to anticipate progress." (AR 53.) Anderson was provided occupational therapy with the goal of improving her ability to care for herself and enabling her to prepare a simple meal. Treatment notes from her therapist document how Anderson was expected to and did in fact improve from this therapy, ultimately preparing a meal of oatmeal independently. (AR 208, 211-16.)

The Secretary now claims that these services, regardless of Anderson's rehabilitation potential, were not sufficiently complex or sophisticated to constitute a skilled service. (Doc. 34 at 21.) But that argument provides no defense to the ALJ's unsupported finding that occupational therapy was a fool's errand destined to fail. Whether Anderson's occupational therapy was, either inherently or in light of any "special medical complications," a skilled service is something to be considered on remand, not answered here as a way to salvage the Secretary's decision. *See* 42 C.F.R. § 409.44(c)(2)(ii); *MBPM* § 40.2.1.

For these reasons, the Secretary's decision must be reversed because it is not supported by substantial evidence. On remand, the Secretary must also consider whether Anderson required skilled therapy to either establish or perform a maintenance program in accordance with 42 C.F.R. § 409.44(c)(2)(iii).

B. Physician Certifications

For each of the challenged periods, Dr. Mann signed a form entitled "Home Health Certification and Plan of Care." (AR 170-72, 605-09, 610-11, 915-16, 1238-40.) These forms represent Dr. Mann's certification that Anderson required the ordered home health services that she received, and also contain a brief narrative about Anderson's condition, prognosis, and plan of care. *Id*. The ALJ did not discuss or even mention these certifications in her written decisions, and Anderson argues that this omission constitutes reversible error. She essentially claims that these certifications are tantamount to Dr. Mann's opinion as a treating physician, and are therefore entitled to "some extra" evidentiary weight in the absence of a specific reason as to why they are not.

In Social Security disability cases, the "treating physician rule" affords controlling weight to a treating physician's opinion when it is well supported by medically acceptable clinical techniques and is not inconsistent with the other substantial evidence. 20 C.F.R. § 404.1527(d); *see also Green-Younger v. Barnhart*, 335 F.3d 99, 106 (2d Cir. 2003). In the Medicare context, by contrast, the Second Circuit has explicitly left to the Secretary the initial determination of the weight to be given to a treating physician's opinion. *New York ex rel. Stein v. Sec'y of Health & Human Servs.*, 924 F.2d 431, 433-34 (2d Cir. 1991). Nonetheless, the Second Circuit has advised that, "we would expect the Secretary to place significant reliance on the informed opinion of a treating physician and either apply the treating physician rule, with its component of 'some extra weight' to be accorded that opinion, . . . or to supply a reasoned basis . . . for declining to do so." *State of N.Y. on behalf of Holland v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991).

Following this guidance from *Holland*, this Court has consistently required the Secretary to either give "some extra weight" to treating physician opinions, or to provide a reasoned basis for not doing so.[7] *See*, *e.g.*, *OVHA ex rel. Carey v. Sebelius*, 698 F. Supp. 2d 436, 441 (D. Vt. 2010); *Dennis v. Shalala*, 1994 WL 708166, at *3 (D. Vt. Mar. 4, 1994); *Smith*, 855 F. Supp. at 664; *Bergeron*, 855 F. Supp. at 668; *Folland*, 1992 WL 295230 at *4. Here, there is no dispute that the ALJ ignored Dr. Mann's certifications in her written decisions, so the question is whether these certifications rise to the level of a physician's opinion to which this case law applies.

In the recent case of *Carey v. Sebelius*, this Court clarified that certifications are not generally equivalent to a treating physician's opinion, "but instead . . . are a relevant part of the factual record when determining coverage." 698 F. Supp. 2d at 441. But because the physician certifications at issue in *Carey* were specifically tailored to the individual claimant, and because they were "explained and supported by the entire record," the Court found that they "should have been afforded substantial weight" in that context. *Id*. at 438. Thus, the Court took a common sense approach, recognizing that a certification is not necessarily precluded from containing a physician's opinion merely because it is formally referred to as a "certification." And under certain circumstances, such as when a certification contains substantive commentary about a patient's individualized condition rather than mere "checked boxes," and when no other physician

[7] This interpretation of *Holland* is not universal, as other courts have considered its admonition to be "obvious[ly]" nothing more than speculation as to how a treating physician rule in the Medicare context might work, were it adopted. *Arruejo v. Thompson*, 2001 WL 1563699, at *13-14 (E.D.N.Y. July 3, 2001).

reports conflicting evidence on the patient's condition, the opinion reflected in the certifications should be afforded some extra evidentiary weight. *Id*.

Notwithstanding *Carey*, however, it remains true that "a certification does not bind the Secretary to a finding of eligibility," *Smith*, 1992 WL 295230, at *4 n.1 (citing *Bodnar*, 903 F.2d at 125), and that the Second Circuit has not definitively applied the treating physician rule to Medicare cases. *Kaplan v. Leavitt*, 503 F. Supp. 2d 718, 723 (S.D.N.Y. 2007) (citing *Keefe v. Shalala*, 71 F.3d 1060, 1064 (2d Cir. 1995)). And both here and in future cases, the Court must take care to ensure that these rules are not swallowed by the exception that certifications may, under certain circumstances, be entitled to some extra evidentiary weight.

In this case, Dr. Mann's certifications are not distinguishable from those at issue in *Carey*, and therefore it was error for the ALJ to ignore them without providing a reasoned explanation. As in *Carey*, the certifications indicate that Anderson was under Dr. Mann's care, and the medical record shows that Dr. Mann in fact treated Anderson in person. (AR 181.) The certifications contain orders specific to Anderson's plan of care, as well as narratives about Anderson's current condition, progress, and prognosis. In addition, no other doctor reported conflicting information. Finally, the medical record as a whole supports Dr. Mann's certification that Anderson required skilled services throughout the disputed periods. This is most evident with regard to physical and occupational therapy, as the therapist notes show that Anderson improved in her mobility and activities of daily living much as Dr. Mann expected. *See* Part IV. A., *supra*.

As the Court noted in *Carey*, such certifications are distinguishable from those in cases such as *Cardinal v. Thompson*, No. 2:00-CV-349 (D. Vt. Oct. 26, 2001) and *Pope v. Sec'y of Health & Human Servs.*, 1991 WL 236173, at *6 (D. Vt. Aug. 28, 1991), which were deemed to not constitute physician opinions. Unlike the more substantive and individualized certifications signed by Dr. Mann, the certifications at issue in both *Cardinal* and *Pope* were merely "forms containing a box checked by the attending physician," and were void of any "accompanying explanation tying the claim to the particular patient." *Pope*, 1991 WL 236173, at *6; *see also Cardinal*, Slip. Op. at 12-13. Given the "conclusory" nature of the certifications in those cases, the Secretary "acted properly in not giving" them "controlling weight in light of other inconsistent substantial evidence." *Cardinal*, Slip. Op. at 13.

Under the circumstances present in this case, by contrast, the ALJ should have afforded some extra weight to Dr. Mann's opinion as reflected in his physician certifications and supported by the record, or provided a reasoned basis for declining to do so. Her failure to do either was error.

C. Patient Education and Skilled Management of Care

Finally, the ALJ erred in two additional respects by not adequately considering whether Anderson required skilled patient education or care management.

Dr. Mann certified patient education regarding management of type II diabetes and a diabetic diet for each of the four disputed certification periods. (AR 172, 606, 915, 1238.) "Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance." 42 C.F.R. §

409.33(a)(3)(i). For example, "a patient newly diagnosed with diabetes requires instruction from technical or professional personnel to learn the self-administration of insulin or foot-care precautions." 42 C.F.R. § 409.33(a)(3)(ii); *see also MBPM* § 40.1.2.3 (providing that a skilled nurse may be required to teach a "newly diagnosed diabetic," or his or her caregivers, "all aspects of diabetes management, including how to . . . follow a diabetic diet").

In this case, the ALJ provided no explanation whatever as to why Anderson was not covered for the patient education that Dr. Mann certified. It is true that, as the Secretary now points out, "after a reasonable period of time, if it becomes apparent that the teaching or training is unsuccessful, or that the patient is unable to learn, then further teaching would cease to be reasonable and necessary." *Smith*, 855 F. Supp. at 662; *see also* 42 C.F.R. § 409.42(c)(1)(ii). And it may be that patient education was no longer reasonable and necessary for Anderson after the first certification period for which she received coverage. But none of this explains why the ALJ failed to consider patient education at all in her analysis. The Court cannot now "confidently say that no reasonable factfinder, following the correct analysis," could find that Anderson's education services were reasonable and necessary, and therefore coverage for Anderson's diabetic education must be considered on remand. *Fitzgerald v. Astrue*, 2009 WL 4571762, at *9 (D. Vt. Nov. 30, 2009).

With regard to skilled management and evaluation of Anderson's care plan, the ALJ denied coverage because the "personal care services provided to [Anderson] were not so complex that they required the management of professional personnel." (AR 52,

495, 785, 1109.) This analysis is deficient because there is no indication that the ALJ considered either the aggregate of services received by Anderson, or whether skilled management was reasonable and necessary in light of Anderson's unique condition, regardless of the otherwise (supposed) simplistic nature of the services she received. *See Hurley v. Bowen*, 857 F.2d 907, 911 (2d Cir. 1988) ("Overall management and evaluation of a care plan may be considered a skilled service, and the *aggregate* of services provided by non-professionals may require the involvement of technical or professional personnel to evaluate and manage their provision.") (emphasis added); *Smith*, 855 F. Supp. at 663 ("If the patient's age and the nature of her condition create a high potential for serious complications, only a skilled professional would have the ability to understand the relationship and effect of the various services provided."). Further, the ALJ's analysis wrongfully excludes the possibility that the *skilled* services certified for Anderson required skilled management and evaluation. The ALJ considered only Anderson's "personal care services," for which Medicare does not provide coverage, 42 C.F.R. § 409.33(d), and which does not include any of the skilled services ordered by Dr. Mann in this case.

Given these legal errors, the Secretary must assess on remand whether Anderson is entitled to Medicare coverage for patient education and overall management and evaluation.

V. Anderson is Not Entitled to Declarative, Injunctive, or Mandamus Relief

Because the Court rejects Anderson's claim of a stability presumption, she is not entitled to the declarative, injunctive, or mandamus relief that she requests. (Doc. 3,

Compl. at 8-9.) Arguing otherwise, Anderson cites *Schisler v. Heckler*, 787 F.2d 76 (2d Cir. 1986) and contends that equitable relief is appropriate even if the unlawful presumption was not intentionally applied in this case. But *Schisler* is plainly distinguishable, and Anderson's argument is without merit.

In *Schisler*, a Social Security disability class action, the plaintiffs sought an injunction requiring the Social Security Administration ("SSA") to properly apply the treating physician rule to each of their individual claims on remand. *Id*. at 81. The court found that the "SSA [had] in fact adopted the treating physician rule," but nonetheless issued an injunction ordering the SSA to "state in relevant publications . . . that adjudicators at all levels . . . are to apply the treating physician rule of this circuit." *Id*. at 84. Anderson seeks a similar injunction here, one proscribing presumptive denials of coverage for stable claimants at all levels of Medicare adjudication, and she believes it is warranted even if the Secretary did not presumptively deny coverage in this case.

Schisler does not control here for two independent reasons. First, Anderson has not shown the same widespread and historical use of the challenged improper standard that justified the injunction in *Schisler*. There, the court noted that cases reversing the SSA for failing to apply the treating physician rule were "almost legion." *Id*. at 82 (quoting *De Leon v. Heckler*, 734 F.2d 930, 937 (2d Cir. 1984)). Here, Anderson has offered only one twenty-three year old case, *Fox v. Bowen*, finding that Medicare adjudicators wrongfully denied coverage based on a presumption rather than considering the claimants' individual clinical needs. 656 F. Supp. at 1248. Additional cases cited by Anderson are not on point. Class action plaintiffs raised a similar issue in *Rizzi v.*

Shalala, 1994 WL 686630 (D. Conn. Sept. 29, 1994), but their claims were dismissed as moot. *Id*. at *5. And the legal error found by this Court in *Folland* and *McDonald* was the improper use of hindsight to assess patient stability, and not the very different problem of presumptively denying coverage for stable patients. *See* Part II. C., *supra*.

Second, the *Schisler* court issued the injunction because, while declaring at oral argument that it accepted the treating physician rule, the SSA had not yet published instructions as to the content of that rule. Absent those instructions, the court found, "the danger that [Social Security] adjudicators will apply the wrong legal rule to the facts will be great." *Schisler*, 787 F.2d at 84. Here, by contrast, the Secretary has enacted regulations and published manual provisions that plainly proscribe the very sort of presumptive denials that Anderson alleges in this case. *See*, *e.g.*, 42 C.F.R. § 409.44(b)(3)(iii); *MBPM* § 20.3; *Rizzi*, 1994 WL 686630 at * 5 ("it is reasonable to conclude that the revised guidelines prohibit any arbitrary presumptions or use of illegal 'rules of thumb' to deny patients with chronic or stable illnesses home health coverage.").

Under the circumstances present in this case, which are very different from those in *Schisler*, neither injunctive nor declaratory relief is warranted.

Conclusion

For the foregoing reasons, the Court recommends that Anderson's Motion to Reverse (Doc. 30) be GRANTED, and that the Secretary's Motion to Affirm (Doc. 34) be DENIED. This matter should be REMANDED for further proceedings consistent with this Report and Recommendation. Because the Court rejects Anderson's claim of an

unlawful presumption applied to deny coverage for stable and chronic patients, she is not entitled to declarative, injunctive, or mandamus relief.

Dated at Burlington, in the District of Vermont, this 27th day of August, 2010.

/s/ John M. Conroy
John M. Conroy
United States Magistrate Judge

Any party may object to this Report and Recommendation within 14 days after service by filing with the clerk of the court and serving on the magistrate judge and all parties, written objections which shall specifically identify the portions of the proposed findings, recommendations or report to which objection is made and the basis for such objections. Failure to file objections within the specified time waives the right to appeal the District Court's order. *See* Local Rules 72(a), 72(c), 73(e); 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b), 6(a) and 6(d).